NUTRESTORE- glutamine powder, for solution
Emmaus Medical, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use NUTRESTORE® safely and effectively. See full prescribing information for NUTRESTORE®.

NUTRESTORE® [L-glutamine powder for oral solution]
Initial U.S. Approval: 2004

INDICATIONS AND USAGE

NutreStore® is an amino acid indicated for:

- the treatment of Short Bowel Syndrome in patients receiving specialized nutritional support when used in conjunction with a recombinant human growth hormone that is approved for this indication (1)

DOSAGE AND ADMINISTRATION

- 30 g daily in divided doses (5 g taken 6 times each day orally) for up to 16 weeks (2)
- Each dose should be reconstituted in 8 oz (250 mL) of water prior to consumption (2)
- Should be taken with meals or snacks at 2- to 3-hour interval while awake (2)

DOSAGE FORMS AND STRENGTHS

- Pre-printed paper-foil-plastic laminate packets: 5 g powder (3)

CONTRAINDICATIONS

- None (4)

WARNINGS AND PRECAUTIONS

- Routine monitoring of renal and hepatic function is recommended in patients receiving lPN, particularly in those with renal or hepatic impairment (5.1)

ADVERSE REACTIONS

Most common adverse reactions are (6.1):

- In initial four (4) weeks (incidence >10%): flatulence, abdominal pain, nausea, tenesmus, vomiting, hemorrhoids, mouth dry.
- In weeks 5-18 (incidence >10%): nausea, vomiting, tenesmus, pancreatitis, constipation, Crohn's disease aggravated, gastric ulcer, gastrointestinal fistula.

To report SUSPECTED ADVERSE REACTIONS, contact Emmaus Medical, Inc. at 1-877-420-6493 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*
See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 7/2014

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATION AND USAGE

NutreStore® [L-glutamine powder for oral solution] is indicated for the treatment of Short Bowel Syndrome (SBS) in patients receiving specialized nutritional support when used in conjunction with a recombinant human growth hormone that is approved for this indication [*see Dosage and Administration (2)*].

NutreStore and recombinant human growth hormone (rhGH) therapy should be used in conjunction with optimal management of SBS. Optimal management of SBS may include a specialized oral diet, enteral feedings, parenteral nutrition, fluid and micronutrient supplements. A specialized oral diet may consist of a high carbohydrate, low-fat diet, adjusted for individual patient requirements and preferences.

Routine monitoring of renal and hepatic function is recommended in patients receiving NutreStore and intravenous parenteral nutrition (IPN), particularly in those with renal or hepatic impairment. Glutamine is metabolized to glutamate and ammonia, which may increase in patients with hepatic dysfunction.

The safety and efficacy of NutreStore have not been studied beyond 16 weeks of treatment.

2 DOSAGE AND ADMINISTRATION

NutreStore should be administered as a cotherapy with rhGH (see prescribing information for somatropin [rDNA origin)] for injection) followed by continued NutreStore for up to 16 weeks.

The recommended dosage of NutreStore is 30 g daily in divided doses (5 g taken 6 times each day orally) for up to 16 weeks. Each dose of NutreStore (5 g) should be reconstituted in 8-oz (250-mL) of water prior to consumption.

NutreStore should be taken with meals or snacks at 2- to 3-hour intervals while awake. The volume of water may be varied according to the patient's preference. In the event of a patient's transient intolerance

to oral intake, a dose may be delayed for up to 2 hours.

3 DOSAGE FORMS AND STRENGTHS

NutreStore is supplied in preprinted paper-foil-plastic laminate packets containing 5 g of L-glutamine powder.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Increased Serum Ammonia and Glutamate

Glutamine is metabolized to glutamate and ammonia, which may increase in patients with hepatic dysfunction. Therefore, routine monitoring of renal and hepatic function is recommended in patients receiving intravenous parenteral nutrition (IPN) and NutreStore, particularly in those with renal or hepatic impairment.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice

Table 1 provides the number of subjects by system-organ class experiencing at least one adverse reaction during the 4-week treatment period of the SBS study. To be listed in Table 1, an adverse reaction must have occurred in more than 10% of subjects in any treatment group.

Table 1 Controlled Trial Adverse Reactions - Initial 4 Week Treatment Period

Adverse Reactions	Group A rhGH+SOD* N=16 n (%)	Group B rhGH+SOD[GLN]* N=16 n (%)	Group C SOD[GLN]* N=9 n (%)
Total Number of Subjects with At Least One Adverse Reaction	16 (100)	16 (100)	8 (89)
Body as a Whole: General Disorders	**15 (94)**	**15 (94)**	**4 (44)**
Edema, Peripheral	11 (69)	13 (81)	1 (11)
Edema, Facial	8 (50)	7 (44)	0(0)
Pain	3 (19)	1 (6)	1 (11)
Chest Pain	3 (19)	0 (0)	0 (0)
Fever	0 (0)	1 (6)	2 (22)
Back Pain	1 (6)	0 (0)	1 (11)
Flu-like Disorder	0 (0)	1 (6)	1 (11)
Malaise	2 (13)	0 (0)	0 (0)
Edema, Generalized	2 (13)	0 (0)	0 (0)
Abdomen Enlarged	0 (0)	0 (0)	1 (11)
Allergic Reaction	0 (0)	0 (0)	1 (11)

Rigors (Chills)	0 (0)	0 (0)	1 (11)
Gastrointestinal System Disorders	**12 (75)**	**12 (75)**	**6 (67)**
Flatulence	4 (25)	4 (25)	2 (22)
Abdominal Pain	4 (25)	2 (13)	1 (11)
Nausea	2 (13)	5 (31)	0 (0)
Tenesmus	1 (6)	3 (19)	3 (33)
Vomiting	3 (19)	3 (19)	1 (11)
Hemorrhoids	1 (6)	0 (0)	1 (11)
Mouth Dry	1 (6)	0 (0)	1(11)
Musculoskeletal System Disorders	**7 (44)**	**7 (44)**	**1 (11)**
Arthralgia	7(44)	5 (31)	0 (0)
Myalgia	2 (13)	0 (0)	1 (11)
Resistance Mechanism Disorders	**6 (38)**	**3 (19)**	**4 (44)**
Infection	0 (0)	1 (6)	3 (33)
Infection Bacterial	3 (19)	0 (0)	1 (11)
Infection Viral	1 (6)	2 (13)	0 (0)
Moniliasis	2 (13)	0 (0)	0 (0)
Application Site Disorders	**5 (31)**	**4 (25)**	**1 (11)**
Injection Site Reaction	3 (19)	4 (25)	1 (11)
Injection Site Pain	5 (31)	0 (0)	0 (0)
Central and Peripheral Nervous System Disorders	**4 (25)**	**4 (25)**	**2 (22)**
Dizziness	1 (6)	2 (13)	0 (0)
Headache	1 (6)	1 (6)	1 (11)
Hypoasthesia	1 (6)	1 (6)	1 (11)
Skin and Appendages Disorders	**4 (25)**	**4 (25)**	**2 (22)**
Rash	1 (6)	2 (13)	0 (0)
Pruritis	0 (0)	1 (6)	1 (11)
Sweating Increased	2 (13)	0 (0)	0 (0)
Nail Disorder	0 (0)	0 (0)	1 (11)
Respiratory System Disorders	**1 (6)**	**5 (31)**	**1 (11)**
Rhinitis	0 (0)	3 (19)	1 (11)
Metabolic and Nutritional Disorders	**3 (19)**	**1 (6)**	**1 (11)**
Dehydration	3 (19)	0 (0)	1 (11)
Thirst	0 (0)	0 (0)	1 (11)
Urinary System Disorders	**2 (13)**	**1 (16)**	**1 (11)**
Pyelonephritis	0 (0)	0 (0)	1 (11)
Psychiatric Disorders	**1 (6)**	**0 (0)**	**2 (22)**
Depression	0 (0)	0 (0)	2 (22)
Reproductive Disorders, Female	**2 (13)**	**0 (0)**	**1 (11)**
Breast Pain Female	1 (6)	0 (0)	1 (11)
Hearing and Vestibular Disorders	**0 (0)**	**2 (13)**	**0 (0)**
Ear or Hearing Symptoms	0 (0)	2 (13)	0 (0)

GROUP A: rhGH + SOD for 4 weeks followed by SOD for 12 weeks.

GROUP B: rhGH + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks.

GROUP C: rhGH placebo + SOD [GLN] for 4 weeks followed by SOD [GLN) for 12 weeks.

* SOD [GLN) = Specialized Oral Diet supplemented with Glutamine; rhGH + SOD = Human Growth Hormone plus Specialized Oral Diet; rhGH + SOD [GLN] = Human Growth Hormone plus Specialized Oral Diet

supplemented with Glutamine

Table 2 summarizes the number of subjects by system-organ class who experienced an AR during weeks 5 to 18 of the randomized, controlled SBS study. To be listed in Table 2, an AR must have occurred in more than 10% of subjects in any treatment group.

Table 2 Controlled Trial Adverse Reactions -Weeks 5 to 18

Adverse Reactions	Group A rhGH+SOD* N=15 n (%)	Group B rhGH+SOD[GLN]* N=16 n (%)	Group C SOD[GLN]* N=9 n (%)
Total Number of Subjects with At Least One Adverse Reaction	**12 (80)**	**13 (81)**	**7 (78)**
Gastrointestinal System Disorders	**7 (47)**	**7 (44)**	**3 (33)**
Nausea	3 (20)	0 (0)	2 (22)
Vomiting	2 (13)	3 (19)	0 (0)
Abdominal Pain	3 (20)	1 (6)	0 (0)
Tenesmus	0 (0)	3 (19)	1 (11)
Pancreatitis	0 (0)	1 (6)	1 (11)
Constipation	0 (0)	0 (0)	1 (11)
Crohn's Disease Aggravated	0 (0)	0 (0)	1 (11)
Gastric Ulcer	0 (0)	0 (0)	1 (11)
Gastrointestinal FistuIa	0 (0)	0 (0)	1 (11)
Resistance Mechanism Disorders	**6 (40)**	**5 (31)**	**5 (56)**
Infection Bacterial	0 (0)	2 (13)	3 (33)
Infection Viral	3 (20)	1 (6)	1 (11)
Infection	1 (7)	2 (13)	1 (11)
Sepsis	3 (20)	1 (6)	0 (0)
Body as a Whole: General Disorders	**4 (27)**	**2 (13)**	**1 (11)**
Fever	2 (13)	1 (6)	1 (11)
Fatigue	2 (13)	0 (0)	0 (0)
Respiratory System Disorders	**2 (13)**	**4 (25)**	**1 (11)**
Rhinitis	1 (7)	3 (19)	0 (0)
Laryngitis	0 (0)	0 (0)	1 (11)
Pharyngitis	0 (0)	0 (0)	1 (11)
Reproductive Disorders, Female	**0 (0)**	**4 (25)**	**1 (11)**
Vaginal Fungal Infection	0 (0)	0 (0)	1 (11)
Skin and Appendages Disorders	2 (13)	2 (13)	1 (11)
Rash	1 (7)	0 (0)	1 (11)
Musculoskeletal System Disorders	**2 (13)**	**2 (13)**	**0 (0)**
Arthralgia	2 (13)	2 (13)	0 (0)
Psychiatric Disorders	**0 (0)**	**1 (6)**	**1 (11)**
Depression	0 (0)	0 (0)	1 (11)
Insomnia	0 (0)	0 (0)	1 (11)
Urinary System Disorders	**0 (0)**	**0 (0)**	**2 (22)**
Pyelonephritis	0 (0)	0 (0)	1 (11)
Renal Calculus	0 (0)	0 (0)	1 (11)
Application Site Disorders	**0 (0)**	**0 (0)**	**1 (11)**

Injection Site Reaction	0 (0)	0 (0)	1 (11)
Liver and Biliary System Disorders	**0 (0)**	**0 (0)**	**1 (11)**
Hepatic Function Abnormal	0 (0)	0 (0)	1 (11)
Vascular Extracardiac Disorders	**0 (0)**	**0 (0)**	**1 (11)**
Vascular Disorder	0 (0)	0 (0)	1 (11)

GROUP A: rhCH + SOD for 4 weeks followed by SOD for 12 weeks.

GROUP B: rhGH + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks.

GROUP C: rhGH placebo + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks.

* SOD [GLNJ = Specialized Oral Diet supplemented with Glutamine; rhGH + SOD = Human Growth Hormone plus Specialized Oral Diet; rhGH + SOD [GLN] = Human Growth Hormone plus Specialized Oral

During the initial 4-week treatment period, 100% of patients receiving growth hormone with and without glutamine reported at least one AR, whereas 89% of patients receiving growth hormone placebo with glutamine reported at least one AR. During weeks 5 to 18, 81% of patients receiving growth hormone with glutamine, 80% of patients receiving growth hormone without glutamine and 78% of patients receiving growth hormone placebo with glutamine experienced at least one AR. There were no deaths in this study.

7 DRUG INTERACTIONS

Formal drug interaction studies have not been conducted.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects: Pregnancy Category C

Animal reproduction studies have not been conducted with glutamine. It is also not known whether glutamine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Glutamine should be given to a pregnant woman only if clearly needed.

8.2 Labor and Delivery

The effect of L-glutamine on labor and delivery is unknown.

8.3 Nursing Mothers

It is not known whether L-glutamine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when L-glutamine is administered to a nursing woman.

8.4 Pediatric Use

The safety and effectiveness of L-glutamine in pediatric patients have not been established.

8.5 Geriatric Use

The clinical trial enrolled SBS patients between the ages of ZO and 75 years. Only 8 of the 41 subjects evaluated were ≥65 years of age. The clinical trial of oral glutamine did not include sufficient numbers of subjects aged 65 years and over to determine if they respond differently than younger subjects. In general, dose selection for an elderly patient should be individualized, because of the greater frequency of decreased hepatic, renal, or cardiac function, as well as concomitant disease in this population.

8.6 Hepatic Impairment

Glutamine is metabolized to glutamate and ammonia, which may increase in patients with hepatic dysfunction. Therefore, routine monitoring of hepatic function is recommended in patients receiving intravenous parental nutrition (IPN) and NutreStore.

8.7 Renal Impairment

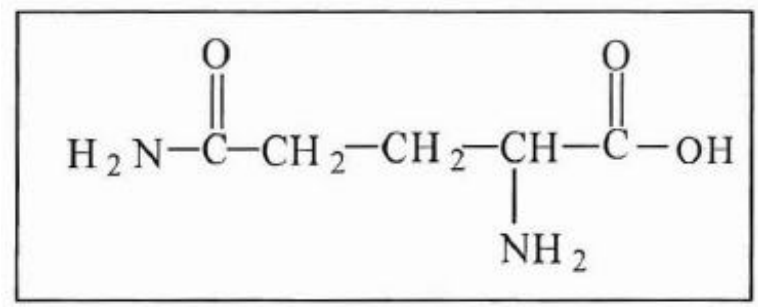
Glutamine is metabolized to glutamate and ammonia. Routine monitoring of renal function is recommended in patients receiving intravenous parental nutrition (IPN) and NutreStore.

10 OVERDOSAGE

Single oral doses of glutamine at about 20 to 22 g/kg, 8 to 11 g/kg, and 19 g/kg were lethal in mice, rats, and rabbits, respectively.

11 DESCRIPTION

NutreStore (L-glutamine powder for oral solution) for oral administration is formulated as a white crystalline powder in a paper-foil-plastic laminate packet. Each packet of NutreStore contains 5 g of L-glutamine. The amino acid glutamine is also known as (S)-2-aminoglutaramic acid, L-glutamic acid 5-amide, (S)-2,5-diamino-5-oxopentanoic acid, or L-glutamine. The molecular formula of glutamine is $C_5H_{10}N_2O_3$, and the molecular weight is 146.15 d. Glutamine has the following structural formula:



12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

L-glutamine has important functions in regulation of gastrointestinal cell growth, function, and regeneration. Under normal conditions, glutamine concentration is maintained in the body by dietary intake and synthesis from endogenous glutamate. Data from clinical studies indicate that the role of and nutritional requirements for glutamine during catabolic illness, trauma, and infection may differ significantly from the role of and nutritional requirements for glutamine in healthy individuals. Glutamine concentrations decrease and tissue glutamine metabolism increases during many catabolic disease states, and thus glutamine is often considered a "conditionally essential" amino acid.

12.2 Pharmacodynamics

When glutamine was administered in combination with rhGH to rats, villous height, bowel growth, plasma insulin-like growth factor I, and body weight were significantly higher than in rats treated with either glutamine or rhGH alone.

12.3 Pharmacokinetics

The pharmacokinetics of L-glutamine as described below are based on literature data in healthy subjects. The pharmacokinetics in patients with SBS have not been determined. The plasma glutamine concentrations in these patients following oral administration are expected to be highly variable

depending on the length, segment, and presence/ absence of ileal-cecal valve for the remnant bowel.

Absorption

Following single dose oral administration of glutamine at 0.1 g/kg to six subjects, mean peak blood glutamine concentration was 1028 µM (or 150 mcg/mL) occurring approximately 30 minutes after administration. The pharmacokinetics following multiple oral doses have not been adequately characterized.

Distribution

After an intravenous bolus dose in three subjects, the volume of distribution was estimated to be approximately 200 mL/kg.

Metabolism

Endogenous glutamine participates in various metabolic activities, including the formation of glutamate, and synthesis of proteins, nucleotides, and amino sugars. Exogenous glutamine is anticipated to undergo similar metabolism.

Elimination

Metabolism is the major route of elimination for glutamine. Although glutamine is eliminated by glomerular filtration, it is almost completely reabsorbed by the renal tubules. After an IV bolus dose in three subjects, the terminal half-life of glutamine was approximately 1 hour.

Specific Populations

There are no studies to determine the effect of race, age, or gender on the pharmacokinetics of L-glutamine.

Drug-Drug Interactions

No drug-drug interaction studies have been conducted. Because metabolism of glutamine is mediated via non-CYP enzymes, glutamine pharmacokinetics are unlikely to be affected by other agents through CYP enzyme inhibition or induction.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of L-glutamine. Studies to evaluate its potential for impairment of fertility or its mutagenic potential have not been conducted.

14 CLINICAL STUDIES

14.1 Short Bowel Syndrome

A randomized, controlled, 3-arm, double-blind, parallel-group clinical study evaluated the efficacy and safety of oral glutamine as a cotherapy with rhGH in subjects with SBS who were dependent on intravenous parenteral nutrition (IPN) for nutritional support. The primary endpoint was the change in weekly total IPN volume defined as the sum of the volumes of lPN, supplemental lipid emulsion (SLE), and intravenous hydration fluid. The secondary endpoints were the change in weekly IPN caloric content and the change in the frequency of IPN administration per week.

All subjects received a specialized oral diet (SOD) for the duration of the study. Following a two-week equilibration period, treatment was administered in a double blind manner. Group A (N=16) received rhGH for four weeks plus oral glutamine placebo for 16 weeks, Group B (N=16) received rhGH for four weeks plus oral glutamine for 16 weeks, and Group C (N=9), received rhGH placebo for four

weeks plus oral glutamine for 16 weeks. The efficacy of glutamine was assessed by comparing the cotherapy (rhGH and oral glutamine) to rhGH alone.

After 4 weeks of treatment with subcutaneous rhGH (0.1 mg/kg/d) and oral glutamine (30 g/ d) (Group B), subjects with SBS reduced their requirement for IPN volume (-7.7 L/wk), IPN caloric content (-5751 kcal/wk), and weekly frequency of IPN administration (-4.2 d/wk).

Table 3 Results for Endpoints after 4 weeks of Treatment

	Group A rhGH + SOD *	**Group B rhGH + SOD[GLN] ***	**Group C SOD[GLN] ***
Total IPN volume (L/wk)			
Mean at Baseline	**10.3**	**10.5**	**13.5**
Mean Change	**-5.9**	**-7.7†**	**-3.8**
Total IPN Calories (kcal/wk)			
Mean at Baseline	**7634.7**	**7895.0**	**8570.4**
Mean Change	**-4338.3**	**-5751.2**	**-2633.3**
Frequency of IPN or SLE (days/week)			
Mean at Baseline	**5.1**	**5.4**	**5.9**
Mean Change	**-3.0**	**-4.2**	**-2.0**

GROUP A: rhGH + SOD for 4 weeks followed by SOD for 12 weeks.

GROUP B: rhGH + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks.

GROUP C: rhGH placebo + SOD[GLN] for 4 weeks followed by SOD[GLN] for 12 weeks

* **SOD[GLN] = Specialized Oral Diet supplemented with Glutamine; rhGH + SOD = Human Growth Hormone plus Specialized Oral Diet; rhGH + SOD[GLN] = Human Growth Hormone plus Specialized Oral Diet supplemented with Glutamine**

† **p= 0.023, treatment comparison between rhGH + SOD[GLN] versus rhGH+SOD**

IPN volume requirements were Significantly reduced in subjects receiving subcutaneous rhGH and oral glutamine (Group B) when compared with IPN volume requirements in subjects receiving either treatment alone.

Table 4 Persistence of Treatment Effect

Change in lPN* Volume, Calories, and Frequency Week 2 to Week 18 lTT Population			
Endpoint	**Group A [n = 16]**	**Group B [n = 16]**	**Group C [n = 9]**
Change in weekly IPN Volume (L/wk)	-5.9	-7.2	-4.7
Change in weekly IPN Calories (kcal/wk)	-3522.2	-5347.3	-2254.0
Change in weekly IPN frequency (days/wk)	-2.9	-3.9	-1.9

GROUP A: rhGH + SOD for 4 weeks followed by SOD for 12 weeks.

GROUP B: rhGH + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks.

GROUP C: rhGH placebo + SOD[GLN] for 4 weeks followed yv SOD[GLN] for 12 weeks.

* IPN is Total lPN excluding supplemental lipid emulsion (SLE) and hydration fluid.

The change in weekly IPN volume, calories and frequency was assessed from Week 2 to Week 18. The data support that the treatment effect is maintained for 16 weeks. The efficacy of oral glutamine beyond 16 weeks of treatment has not been adequately studied.

16 HOW SUPPLIED/STORAGE AND HANDLING

NutreStore is supplied in preprinted paper-foil-plastic laminate packets containing 5 g of L-glutamine powder and is supplied as follows:

- Carton of 84 packets (NDC 42457-001-84)

Store at 25°C (77°F) with excursions allowed to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature]

17 PATIENT COUNSELING INFORMATION

[See FDA-approved patient labeling]

17.1 Dosing Instructions

NutreStore should be taken with meals or snacks at 2- to 3-hour intervals while awake. The volume of water may be varied according to the patient's preference. In the event of a patient's transient intolerance to oral intake, a dose may be delayed for up to 2 hours.

For additional information concerning NutreStore, contact:

Manufactured for:
Emmaus
MEDICAL, INC.

20725 S. Western Ave., Suite 136
Torrance, CA 90501-1884
Tel: 1-877-420-6493
www.nutrestore.com

FDA-Approved Patient Labeling

Patient Information

NutreStore® (NOO-tre-stor)
[L-glutamine powder for oral solution] (GLOO-tah-min)

Please read this leaflet carefully before you start to use NutreStore® and each time your prescription is refilled since there may be new information. The information in this leaflet does not take the place of regularly talking with your doctor or health care professional.

What is NutreStore®?

NutreStore® is the amino acid L-glutamine, identical to the L-glutamine that your body produces. NutreStore® is used together with a human growth hormone, approved for treating short bowel syndrome [SBS], in patients receiving a specialized diet tailored to meet their individual needs.

Why has my doctor prescribed NutreStore®?

Your doctor prescribed NutreStore® initially in combination with human growth hormone to help decrease your need for intravenous feedings. After treatment in combination with human growth hormone, you will continue to take NutreStore® alone to maintain the treatment effect. During your treatment with NutreStore® you will be taking up to 6 packets of NutreStore® a day. You will also

receive instructions from your doctor or a dietitian on the proper diet you should follow during this treatment period as well as after your treatment is over. Please refer to the patient package leaflet available for human growth hormone for more information on how to take human growth hormone.

What should I tell my doctor before taking NutreStore®?

Tell your doctor about all of your conditions including if you:

- are pregnant or planning to become pregnant. It is not known if NutreStore® can harm your unborn baby.
- are breast feeding. It is not known if NutreStore® passes into your milk and if it can harm your baby. You should talk to your doctor about breastfeeding while taking NutreStore®.
- have liver or kidney problems. Your doctor may do blood tests to check your liver and kidney function while you are taking NutreStore®.
- are older than 65 years of age. Your dose of NutreStore® may need to be adjusted.

Tell your doctor about all the medicines you take including prescription medicines, non-prescription medicines, vitamins, or herbal supplements. It is not known if NutreStore® and other medicines can affect each other.

What should I avoid while taking NutreStore®?

- **Pregnancy.** You should talk to your doctor if you are planning to become pregnant while taking NutreStore®. It is not known whether NutreStore® can affect the ability of a woman to become pregnant. It is also not known whether NutreStore® can cause harm to a fetus when taken by a pregnant woman or if NutreStore® has an effect on labor and delivery.
- **Breastfeeding.** You should talk to your doctor before breastfeeding an infant while taking NutreStore®. It is not known whether the glutamine in NutreStore® can be passed to an infant in mother's milk, and it is not clear whether the drug could harm the infant if it is passed in mother's milk.

What are the possible side effects of NutreStore®?

Many patients taking NutreStore® and human growth hormone for the treatment of SBS experience side effects.

Whether or not you experience side effects, you and your doctor should periodically talk about your general health.

- Your doctor may want to monitor you more closely and ask you to have blood tests done more frequently.

Digestive system.

The possible side effects you may experience while taking NutreStore® include vomiting, hemorrhoids, pancreatitis, aggravation of Crohn's disease, gastric ulcer, and gastrointestinal fistula (opening between stomach and intestine).

The possible related symptoms you may experience while taking NutreStore® include urge to empty bowel, gas, abdominal pain, nausea, dry mouth and constipation.

These side effects and related symptoms may be similar to those you have experienced while being treated for SBS. You should talk to your doctor about these problems before starting an over-the-counter medication to treat these symptoms. It is important for you to follow your doctor's or dietitian's instructions on the type of diet best for you.

Please refer also to the patient package leaflet available for human growth hormone for more information on the possible benefits and side effects of human growth hormone.

Tell your doctor about any side effects that bother you or that do not go away.

These are not all the side effects with NutreStore®. For more information, ask your doctor or

pharmacist.

How should I take NutreStore®?

NutreStore® should be taken up to 6 times a day (every 2 to 3 hours during the day) with a meal or snack. This should be continued every day for as long as your doctor prescribes. Each dose of NutreStore® should be prepared by pouring the contents of one packet into an 8-oz glass of water and stirring for approximately 1 minute. After stirring, you should drink the NutreStore® within 2 hours. If you miss a dose, you should take your next dose as soon as you remember or are able to take it. Do not take more than 6 packets each day.

What kind of food should I eat during my treatment with NutreStore®?

Your doctor or dietitian will prescribe for you the types and quantities of foods you should eat during your treatment with NutreStore®. These foods are not special and can be purchased from your local market. Your likes and dislikes should be taken into consideration when your meal plan is created.

Your doctor or dietitian will advise you on how many times a day you should eat. Your doctor or dietitian will adjust your diet as needed during your treatment with NutreStore®. It is important that you carefully follow the eating plan your doctor or dietitian gives you.

Storage conditions for NutreStore®

Packets of NutreStore® should be stored at room temperature (25°C / 77°F). Expiration dates are stated on product labels. Do not use any damaged packets of NutreStore®. Keep NutreStore® and all medicines out of the reach of children.

General information about prescription medicines

This medication has been prescribed for a particular medical condition. Do not use it for another condition or give this drug to anyone else. If you have any questions, you should speak with your doctor or health care professional. You may also ask your doctor or pharmacist for a copy of the information provided to them with the product. Keep this and all drugs out of the reach of children.

For additional information, you may call the NutreStore® patient hotline at 1-877-420-6493.

PRINCIPAL DISPLAY PANEL - 84 Packet Carton

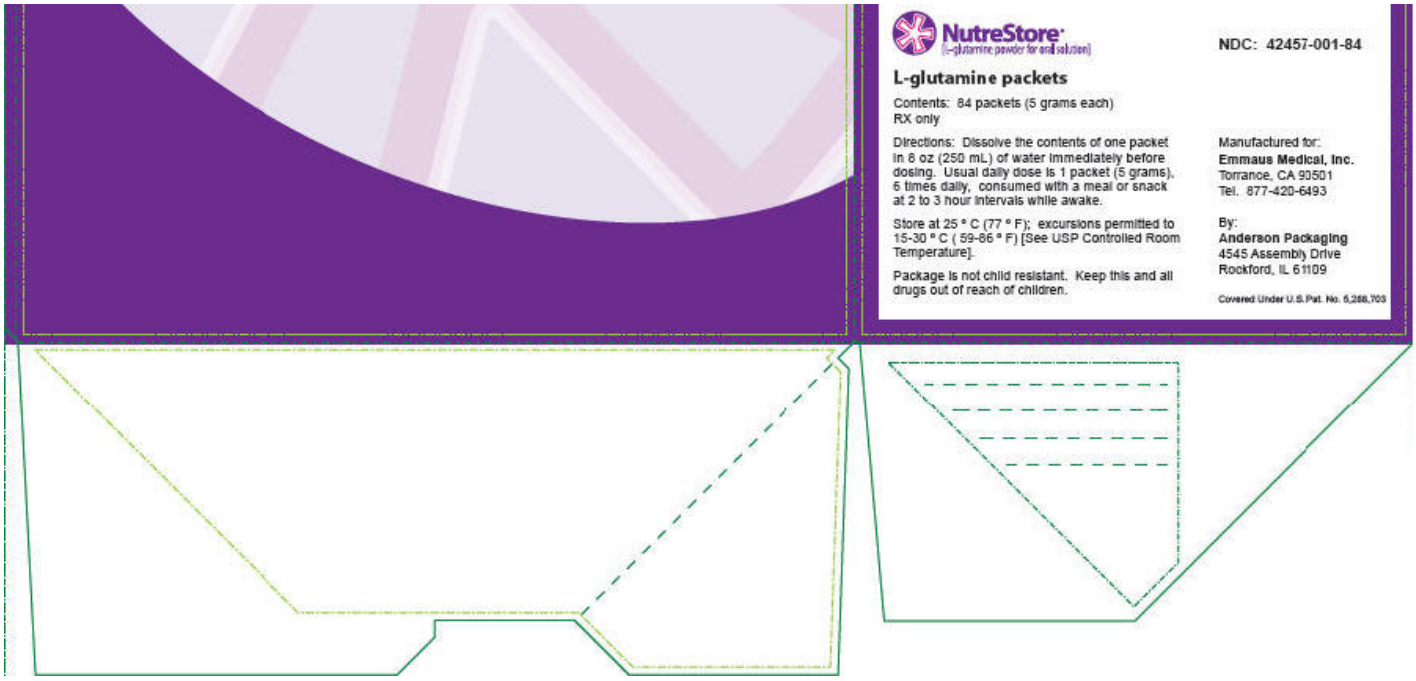
NutreStore®
[L-glutamine powder for oral solution]

NutreStore®

[L-glutamine powder for oral solution]

NutreStore®
[L-glutamine powder for oral solution]

27754-01



NUTRESTORE

glutamine powder, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42457-001
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
glutamine (UNII: 0RH81L854J) (glutamine - UNII:0RH81L854J)	glutamine	5 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:42457-001-84	84 in 1 BOX		
1	NDC:42457-001-01	1 in 1 PACKET		
2	NDC:42457-001-18	18 in 1 BOX		
2	NDC:42457-001-11	1 in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021667	06/04/2008	

Labeler - Emmaus Medical, Inc. (784073434)

Establishment			
Name	**Address**	**ID/FEI**	**Business Operations**
AndersonBrecon Inc.		053217022	PACK(42457-001)

Establishment			
Name	**Address**	**ID/FEI**	**Business Operations**
Kyowa Hakko Bio Co., Ltd.		690598751	API MANUFACTURE(42457-001)

Revised: 7/2014 Emmaus Medical, Inc.